



**ASSOCIATION OF MALAYSIAN MEDICAL INDUSTRIES**

c/o FEDERATION OF MALAYSIAN MANUFACTURERS

Wisma FMM, Persiaran Dagang, PJU 9  
Bandar Sri Damansara, 52200 Kuala Lumpur  
Tel: 603-636 1211 Fax: 603-637 6714

October 28, 1999

Docket Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
Rm 1061  
Rockville  
MD 20852 USA  
Fax: 301 443 8815

Dear sir,

**Comments to the FDA's new proposed Rule.**

The Association of Malaysian Medical Industries (AMMI) under the chairmanship of Encik Yaziz Yunus represents local and multinational companies involved in the development and manufacture of medical devices, products, equipment and services in Malaysia for the healthcare industry worldwide. Established in 1989, the association takes a leading role in promoting the quality of made-in Malaysia products as well as promoting the industry as a strategic sector in Malaysia's industrialisation programme.

In view of the FDA's new proposed rule on new regulations, our association would like to provide the following comments for your reference:

**Sterilization**

If manufacturers decide to sterilize their products using industrial moist heat, ethylene oxide or radiation methods and if they decide to follow the so-called "AAMI" methods to validate and control the process, the manufacturer have to comply "in total" without any modification the following requirements: -

- i. **ANSI/AAMI/ISO 11134** - Sterilization of Healthcare Products - Requirements for validation and Routine Control - Industrial Moist Heat Sterilization.
- ii. **ANSI/AAMI/ISO 11135** - Medical Device - Validation and Routine Control of Ethylene Oxide Sterilization.
- iii. **ANSI/AAMI/ISO 11137** - Sterilization of Healthcare Products - Requirements for Validation and Routine Control - Radiation Sterilization.

The reason for such comments is that there might be tendency to add additional requirements to the already established and accepted "AAMI" guidelines as the guidelines have been accepted by the industry worldwide.

We hope that the above comments are useful for your reference.

Yours sincerely,

Chia Wai Mun  
AMMI Secretariat

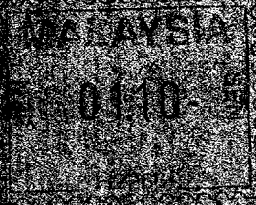
cc: Encik Yaziz Yunus  
Chairman of AMMI (603-6915320)

99D-2335

C13



MEL UDARA  
PAR AVION



PERSEKUTUAN PEKILANG PEKILANG MALAYSIA  
FEDERATION OF MALAYSIAN MANUFACTURERS  
(A Company Limited by Guarantee)  
Wangsa Maju, P. O. Box 12101, 50770 Kuala Lumpur  
Tel. 603-6341211 Fax 603-6341260/547208

20657X0051

ANVT

